

Remarks

This Amendment is in response to the Office Action dated April 17, 2008.

Rejections

35 U.S.C. §112

Claim 32 has been rejected under 35 U.S.C. §112, second paragraph. It is asserted in the Office Action that “[c]laim 32 recites the limitation respective outer and inner surfaces in the first and second layers. There is insufficient antecedent basis for this limitation in the claim.”

Applicants have amended claim 32 and respectfully request withdrawal of this rejection.

35 U.S.C. §102(b)

I. Crocker et al.

Claims 27 and 28

Claims 27-29, 32-37 and 65-68 have been rejected under 35 U.S.C. §102(b) as being anticipated by Crocker et al. (6,120,523). It is asserted in the Office Action that Crocker et al. discloses a focalized intraluminal balloon.

Applicants traverse the rejection.

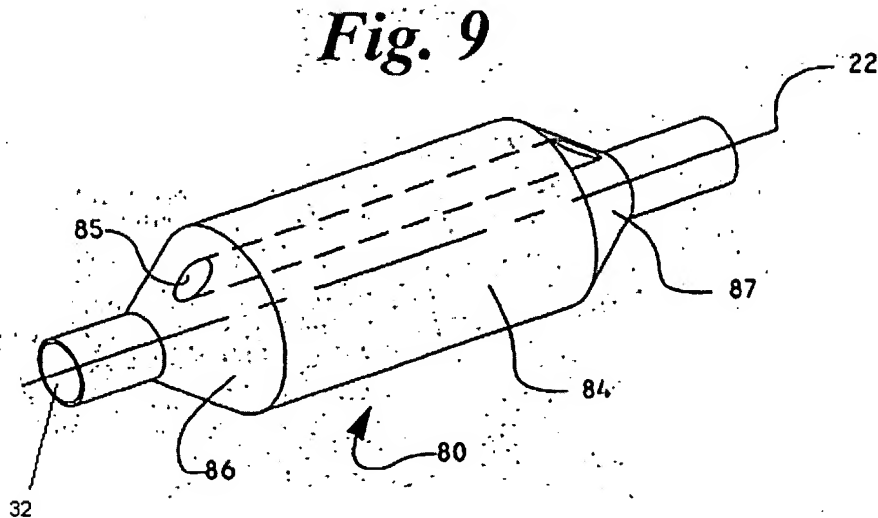
Independent claim 27 is directed to a medical balloon having a longitudinal axis and proximal and distal ends, the balloon formed of a radiation cured polymerizable composition, the balloon connecting to a coaxial shaft at the proximal end thereof and connecting to the same

or a different coaxial shaft at the distal end thereof, and having a central body wall portion between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall portions, respectively, wherein the balloon further comprises a lumen extending longitudinally therethrough, said lumen passing through the tapering proximal and distal wall portions of the balloon.

It is asserted in the Office Action that “[r]egarding claims 27 and 63, Examiner asserts that the balloon pictured in Figure 2 meets the claims limitations as claimed. The lumen (32) of Crocker et al. passes through the tapering distal and proximal wall portions (38, 42) of the balloon.” Office Action, page 9, first paragraph.

This is simply incorrect.

Applicants have included Fig. 9, below, to illustrate lumen 85 of the present invention which passes through the tapering proximal and distal wall portions. Applicants have also included reference numeral 32, which is representative of the guide wire lumen 32 that is disclosed by Crocker et al. and asserted in the Office Action to be the same as lumen 85.



As can be seen from Fig. 9, lumen 85 is clearly not the same as lumen 32, and lumen 32 does not pass through the tapering wall portions of the balloon. Rather, it passes under the tapering wall portion.

Crocker et al. simply fails to disclose or suggest a lumen 85 passing through the tapering distal and proximal wall portions of the balloon. Crocker et al. disclose a guide wire lumen 32 that passes under the tapering proximal and distal wall portions of the balloon, not through them. Fig. 2 of Crocker et al. is reproduced below:

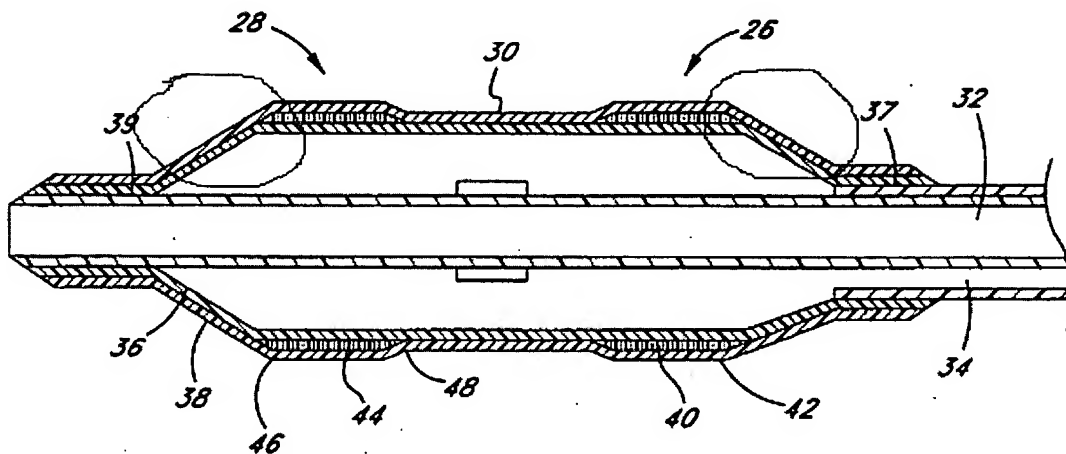


FIG. 2

Applicants have circled the proximal and distal tapering wall portions. As can be seen from Fig. 2, above, there is no lumen extending therethrough as recited in claim 27.

Crocker et al. therefore does not anticipate claim 27 because each and every feature recited in claim 27 is not disclosed by Crocker et al., namely, the lumen extending through the tapering wall portions. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed.

Cir. 1987). See also MPEP 2131.

Claim 28 depends from claim 27 and is not anticipated by Crocker et al. for at least the reasons that claim 27 is not anticipated by Crocker et al.

Claims 32-37

Independent claim 32 is directed to an article having a multi-layer polymeric material film including at least first and second layers, each layer having an inner and an outer surface, the first and second layers being in adherent contact with each other over a coextensive area along respective outer and inner surfaces, each of the first and second layers having an at-rest configuration defining an at-rest area on the respective outer and inner surfaces corresponding to the coextensive area, the at-rest area of the first layer outer surface being smaller than the at-rest area of said second layer inner surface.

It is asserted in the Office Action that:

Regarding claim 32, Examiner asserts that the first (36) and second balloon (48) layers of Crocker et al. meet the claimed limitations of "having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface." Examiner asserts that the outer surface of the first layer (36) has a smaller surface area than the inner surface of the second layer (48) because of the stretched areas (near 44 and 40) which are present to accommodate the expansion limiting bands.

Office Action, page 9, second paragraph.

Applicants submit that Crocker et al. fail to disclose that the at-rest area of the first layer outer surface is smaller than the at-rest area of the second layer inner surface. It is further stated in the Office Action that:

In response to applicants argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies

(i.e., "Crocker et al. is silent as to these bands providing stress so as to collapse the article as disclosed in Applicants' specification") are not recited in the rejected claim(s).

However, the end result of having an at-rest area of the first layer outer surface that is smaller than the at-rest area of the second layer inner surface, is an area on the balloon which is under stress.

Thus, while the claim does not specifically state that the area is under stress, it is an inherent characteristic of the balloon having an at-rest area of a first layer outer surface that is smaller than the at-rest area of the second layer inner surface.

Crocker et al. is silent as to either of these features.

Furthermore, the argument presented on page 9 of the Office Action that Crocker et al. disclose "...the outer surface of the first layer (36) has a smaller surface area then the inner surface of the second layer (48) because of the stretched areas (near 44 and 40) which are present to accommodate the expansion limiting bands" is nonsensical.

Crocker et al. says nothing about stretching any areas near the expansion limiting bands 40, 44 for purposes of accommodating the expansion limiting bands. The disclosure of Crocker et al. is being expanded to make such a statement. Furthermore, Crocker et al. disclose that the expansion limiting bands can be applied by coating or mounting on the balloon, but there is no disclosure that there is any stretching or other stress applied to the balloon to accommodate the structures. See col. 5, lines 57-65.

The only reference that Crocker et al. make to stretching, is for the purpose of necking down the proximal and distal ends to a diameter which relatively closely fits the portion of the tubular catheter body to which to which it is to be sealed, or for purposes of obtaining sections of the balloon with a thinner wall portion, in each instance accompanied by a heat set.

See col. 6, lines 55-59 and col. 8, lines 59-67.

This has nothing whatsoever to do with providing a first layer outer surface having a smaller at-rest area than a second layer inner surface, the result of which is a section of balloon under stress.

As Crocker et al. is silent as to this feature of claim 32, Crocker et al. simply cannot anticipate claim 32.

Claims 33-37 depend from claim 32 and are not anticipated by Crocker et al. for at least the reasons that claim 32 is not anticipated by Crocker et al.

Claims 65-68

Independent claim 65 is directed to a balloon including a balloon body having a proximal end and a distal end, and the balloon comprising circumferential elastic bands at the proximal end or distal end of the balloon body, the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration.

It is asserted in the Office Action that:

Regarding claim 65, Examiner asserts that the bands of Crocker et al. as disclosed as “substantially non-distensible” materials (col 5, ln 20-30), therefore the materials (nylon, polyamide, polyethylene and PET) do have some elasticity and can be considered to fall under the broadest reasonable definition of an “elastic” material (easily resuming original shape after being stretched or expanded; flexible, see elastic. (2007). In The American Heritage® Dictionary of the English Language. Since the materials listed do have expansion recovery and are termed as ‘expansion limiting bands’ they facilitate and undergo some expansion and recovery during balloon inflation and deflation states. Examiner suggests Applicant further clarify the claim with specific elastic characteristics.

Office Action, page 10, 1st full paragraph.

This argument, however, is not fully pertinent to claim 65, because a main feature

of claim 65 has been left out of the argument, namely, that the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration.

Thus, Applicants submit that the elasticity of Crocker et al. expansion limiting bands by itself is irrelevant. Rather, the bands must also have a smaller diameter than the balloon over which they are disposed.

As Crocker et al. teach coating or mounting without any stretching or otherwise putting any stress on the expansion limiting bands, Crocker et al. also does not anticipate this claim.

Crocker et al. disclose that the properties of nondistensibility of the expansion limiting bands is obtained by selecting nondistensible materials or by crosslinking, but not by employing an elastic band having a smaller diameter than the balloon over which it is disposed. See col. 5, lines 33-65. There is absolutely nothing in Crocker et al. to suggest that the expansion limiting bands 40, 44 have a smaller diameter than the underlying balloon layer(s).

Claims 66-68 depend from claim 65 and are not anticipated by Crocker et al. for at least the reasons that claim 65 is not anticipated by Crocker et al.

Applicants respectfully request withdrawal of the rejection of claims 27-29, 32-37 and 65-68 under 35 U.S.C. §102(b) as being anticipated by Crocker et al. (6,120,523). It is asserted in the Office Action that Crocker et al. discloses a focalized intraluminal balloon.

II. Hamlin

Claims 27-28

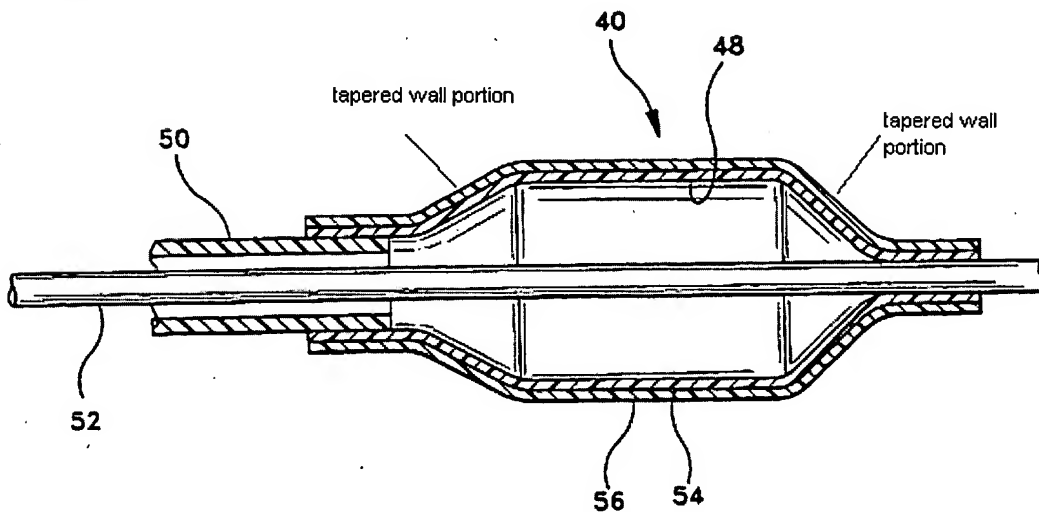
Claims 27-29, 32-35, and 38 have been rejected under 35 U.S.C. §102(b) as being anticipated by Hamlin (6,132,824). It is asserted in the Office Action, page 5, that “the balloon

further comprises a lumen (52) extending longitudinally therethrough, said lumen passing through the proximal and distal wall portions of the balloon (Figures 5-6).”

Applicants disagree.

Applicants have reproduced Fig. 5 of Hamlin below. Inner tubular body 52 disclosed by Hamlin in Figs. 5 and 6, is not the same as Applicants’ lumen 85 which extends through the tapering wall portions of Applicants’ balloon. Applicants have shown the tapered wall portions in Hamlin’s Fig. 5 below.

FIG-5



Therefore, claim 27 is also not anticipated by Hamlin for the same reasons that claim 27 is not anticipated by Crocker et al.

Claim 28 depends from claim 27 and is not anticipated for at least the reasons that claim 27 is not anticipated.

Claims 32-35 and 38

Claim 32 has been discussed above and is directed to an article having a multi-layer polymeric material film including at least first and second layers, each layer having an inner and an outer surface, the first and second layers being in adherent contact with each other over a coextensive area along respective outer and inner surfaces, each of the first and second layers having an at-rest configuration defining an at-rest area on the respective outer and inner surfaces corresponding to the coextensive area, the at-rest area of the first layer outer surface being smaller than the at-rest area of the second layer inner surface.

It is asserted in the Office Action, page 5 that “Hamlin discloses a polymeric balloon that is capable of being radiation cured and is capable of being made of a fluidizable polymer composition, that is comprised of a multi-layer polymeric film (64, 66, 68) wherein a first (64, 66) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 5-6).”

Again, Hamlin fails to disclose or suggest an at-rest area of the first layer outer surface being smaller than the at-rest area of a second layer inner surface wherein the at-rest areas are coextensive.

While Figs. 5 and 6 and the corresponding description discuss multilayers, there is absolutely no disclosure as to an at-rest area of a first layer outer surface being smaller than an at-rest area of a coextensive second layer inner surface, the result of which is an area of the balloon that is under stress. Hamlin discuss the conventional coating and coextruding, but nothing more.

Furthermore, Applicants see no specific disclosure in Hamlin as to the at-rest and open configurations that result in a change in surface area referred to in the Office Action, and even if there was such a reference, such a feature is not the same as that recited in independent claim 32

wherein an first layer outer surface has a smaller area than a second layer inner surface so as to result in an interface that is under stress in the at-rest configuration of the balloon.

As discussed above, while there is no recitation of the “stress” in the claims, this is an inherent result of having a smaller first layer outer surface area that is coextensive with an underlying second layer inner surface area.

Therefore, claim 32 cannot be anticipated by Hamlin because this feature is not disclosed by Hamlin.

Claims 33-35 and 38 depend from claim 32 and are not anticipated by Hamlin for at least the reasons that claim 32 is not anticipated by Hamlin.

Applicants respectfully request withdrawal of the rejection of claims 27-29, 32-35, and 38 under 35 U.S.C. §102(b) as being anticipated by Hamlin (6,132,824).

III. Boussignac et al.

Claims 63-64 have been rejected under 35 U.S.C. §102(b) as being anticipated by Boussignac et al, (5,000,734).

Applicants traverse the rejection.

It is asserted in the Office Action that:

Regarding claims 63-64, Boussignac discloses a medical balloon (1) (Figures 1-2, 4) ... formed of a polymer material (col. 3, ln 25-35), the balloon connecting to a coaxial shaft (3) at the proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof, having a central body wall (near 1) portion connected with tapering wall portions (near 5a, 5b), wherein the balloon comprises a lumen (11) extending therethrough, the lumen spaced apart from the coaxial shaft (Figure 3).”

Office Action, page 4, bottom to page 5, top

Claim 63, has been discussed above, and is directed to a medical balloon formed of radiation cured polymerizable composition connecting to a coaxial shaft at the proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof, and having a central body wall portion between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall portions, respectively, wherein the balloon further comprises a lumen extending therethrough, the lumen spaced apart from the coaxial shaft at the proximal end and the coaxial shaft at the distal end. Other features are recited.

Thus, claim 63 is directed to an embodiment wherein the medical balloon is formed from a radiation cured polymerizable composition.

Boussignac et al. are silent as to forming a balloon from any specific polymer materials whatsoever, much less those that are cured, polymerized, or otherwise reacted, and much less balloons specifically that are polymerized via radiation cure as recited in Applicants' claim 63.

Consequently, claim 63 cannot be anticipated by Boussignac et al. because all of the elements of claim 1 are not specifically disclosed in a single prior art references. See *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d at 1053; and see MPEP 2131.

Claim 64 depends from claim 63 and is not anticipated by Boussignac et al. for at least the reasons that claim 63 is not anticipated by Boussignac et al.

Applicants respectfully request withdrawal of the rejection of claims 63-64 under 35 U.S.C. §102(b) as being anticipated by Boussignac et al, (5,000,734).

IV. White, Jr.

Claim 65

Claim 65 has been rejected under 35 U.S.C. §102(b) as being anticipated by White, Jr. (4,327,734).

Applicants traverse the rejection.

It is asserted in the Office Action that:

Regarding claim 65, White, Jr. discloses a balloon (20) comprising a balloon body (38) having a proximal and distal end, and the balloon comprising circumferential elastic bands (46) at the proximal end or distal end of the balloon body, the elastic bands (46) in their rest configuration have a smaller diameter than the balloon body in its rest configuration (Figure 1) verses the inflated configuration (Figures 2-3) (Figures 1-3).

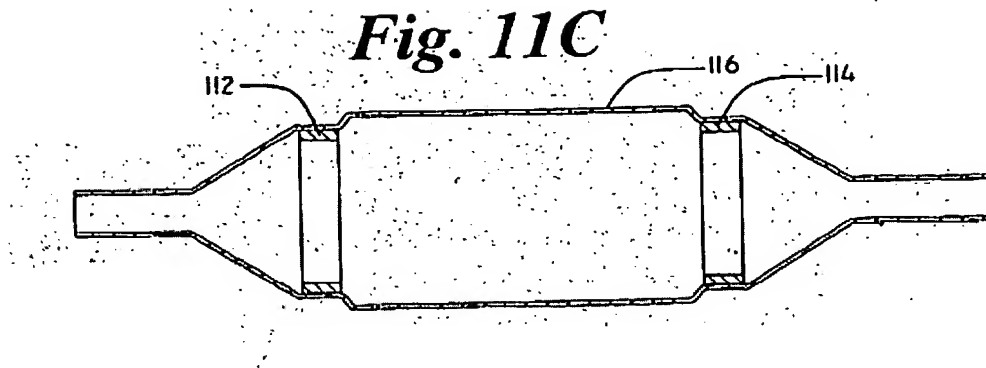
Office Action, page 6

Applicants disagree.

Amended claim 65 is directed to and embodiment of a balloon including a balloon body having a proximal end and a distal end, and the balloon comprising circumferential elastic bands ~~at~~ on the proximal end or distal end of the balloon body, the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration.

The amendment is supported by Fig. 11C.

Fig. 11C has been reproduced below to illustrate the elastic bands 112, 114 located on the proximal end and distal end of the balloon body:



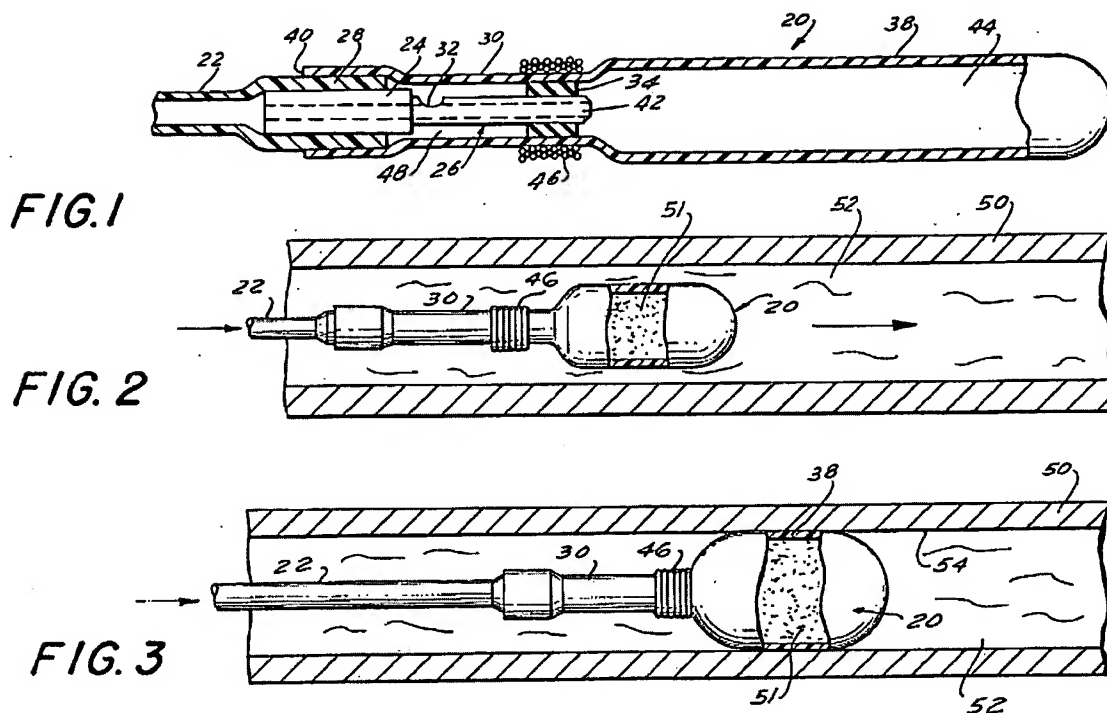
Applicants submit that White, Jr. discloses a balloon catheter assembly including:

... a hollow cannula 22 One end of cannula 22 is adapted to be connected to a source of fluid in a conventional manner. Mounted in the other end of cannula 22 is an enlarged end 24 of a pin 26. The smaller end of the pin 30 is positioned within a self-sealing plug 34 mounted in the open end portion 36 of an expandable balloon 38 ... Surrounding the portion of the balloon where the plug 34 is located on the exterior surface thereof is an elastic band 46 of plastic or rubber material which assists in retaining the pin in the self-sealing plug and is utilized to assist with the self-sealing plug in sealing the open end of the balloon when the cannula and pin combination is removed therefrom during detachment.

Col. 3, lines 12-46

The elastic band 46 disclosed by White, Jr., on the other hand, is not located on the balloon body whatsoever. The location of the elastic bands 112, 114 in the present application is important because the bands have a smaller diameter than the underlying balloon, and are stretched from their at-rest diameter to reach their diameter on a form. When the form has been removed, the composite balloon is stressed by the bands 112, 114 to collapse to their rest position. This aids in obtaining a small deflated profile. See page 17, lines 32-33 to page 18, lines 1-11.

Consequently, as the elastic band 46 disclosed by White, Jr. is not located on the balloon body, it cannot anticipate claim 65. See Figs. 1-3 of White, Jr. below for elastic band 46:



Thus, not all of the elements of claim 65 are disclosed by White, Jr. as required by 35 U.S.C. §102(b). *Id.* at 1053.

Applicant respectfully requests withdrawal of the rejection of claim 65 under 35 U.S.C. § 102(b) as being anticipated by White, Jr. (4,327,734).

V. *Anderson*

Claims 63-64

Claims 63-64 have been rejected under 35 U.S.C. §102(b) as being anticipated by

Anderson (6,007,517).

Applicants traverse the rejection.

It is asserted in the Office Action that:

Regarding claims 63-64, Anderson discloses a medical balloon ... formed of a polymer material, the balloon connecting to a coaxial shaft (2) at the proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof, having a central body wall (near 7) portion connected with tapering wall portions (near 5 and 6), wherein the balloon comprises a lumen (7) extending therethrough, the lumen spaced apart from the coaxial shaft (Figures 3A and 11A)."

Office Action, page 6, bottom to page 7, top.

Claim 63, has been discussed above, and is directed to a medical balloon formed of radiation cured polymerizable composition connecting to a coaxial shaft at the proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof, and having a central body wall portion between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall portions, respectively, wherein the balloon further comprises a lumen extending therethrough, the lumen spaced apart from the coaxial shaft at the proximal end and the coaxial shaft at the distal end. Other features are recited.

Thus, claim 63 is directed to an embodiment wherein the medical balloon is formed from a radiation cured polymerizable composition.

Anderson is silent as to forming a balloon from any polymer material that is cured, polymerized, or otherwise reacted, much less balloons specifically formed by radiation curing polymerization.

Consequently, claim 63 cannot be anticipated by Anderson as required. Id. at 1053.

Claim 64 depends from claim 63 and is not anticipated by Anderson for at least the

reasons that claim 63 is not anticipated by Anderson.

Applicants respectfully request withdrawal of the rejection of claims 63-64 under 35 U.S.C. §102(b) as being anticipated by Anderson (6,007,517).

35 U.S.C. §103(a)

Claims 30-31

Claims 30-31 have been rejected under 35 U.S.C. §103(a) as being obvious over Crocker et al. It is asserted in the Office Action that

Crocker et al meets the claim limitations as described above except for the specific embodiment being used in with a stent or with a rapid exchange catheter ... Crocker et al. teaches a specific medical balloon structure that is disclosed of being used with rapid exchange and for delivery of stents to the vascular system (col 3, ln 40-70, col 4, ln 40-70, see summary of invention) ... it would have been obvious to use the medical balloon as disclosed by the various embodiments and the disclosure of Crocker et al. in order to achieve a versatile controllable balloon element.

Office Action, pp 7-8

Applicants traverse the rejection.

Claims 30-31 depend from claim 27.

Claim 27 has been discussed at length above.

Crocker et al. fail to disclose or suggest a medical balloon having a lumen extending through the tapering wall portions as recited in claim 27.

Therefore, combining a stent or rapid exchange catheter with the balloon fails to render claim 27 obvious because Crocker et al. with a stent or rapid exchange catheter stills fails to disclose or suggest a balloon with a lumen as recited in independent claim 27.

Claims 30-31 are not obvious over Crocker et al, for at least the reasons that claim 27 is not obvious over Crocker et al.

Applicants respectfully request withdrawal of the rejection of claims 30-31 under 35 U.S.C § 103(a) as being unpatentable over Crocker et al.

CONCLUSION

Claims 27-38 and 63-68 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: July 14, 2008

By: /Lisa Ryan-Lindquist/
Lisa R. Lindquist
Registration No.: 43071

6640 Shady Oak Dr., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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